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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0412]

Determination That FOLVITE (Folic Acid), Oral Tablets, 1 Milligram, and Other Drug Products, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

Application No.	Drug Name	Active Ingredient(s)	Strength(s)	Dosage Form/Route	Applicant
NDA 005897	FOLVITE	Folic Acid	1 Milligram (mg)	Tablet; Oral	Wyeth Ayerst Pharms.
NDA 005897	FOLVITE	Folic Acid	5 mg/Milliliter (mL)	Injectable; Injection	Wyeth Ayerst Pharms.
NDA 014691	ALKERAN	Melphalan	2 mg	Tablet; Oral	Apotex Inc.
NDA 015923	HALDOL	Haloperidol Lactate	Equivalent to (EQ) 5 mg Base/mL	Injectable; Injection	Janssen Pharms.
NDA 016042	DYAZIDE	Hydrochlorothiazide; Triamterene	25 mg; 50 mg, 25 mg; 37.5 mg	Capsule; Oral	GlaxoSmithKline
NDA 017959	ADRUCIL	Fluorouracil	50 mg/mL	Injectable; Injection	Pharmacia & Upjohn Co.
NDA 017993	HYDERGINE	Ergoloid Mesylates	0.5 mg, 1 mg	Tablet; Oral	Novartis AG
NDA 018082	DEPAKENE	Valproic Acid	250 mg/5 mL	Syrup; Oral	AbbVie Inc.
NDA 018116	CYCLOCORT	Amcinonide	0.025%, 0.1%	Cream; Topical	Astellas
NDA 018498	CYCLOCORT	Amcinonide	0.1%	Ointment; Topical	Astellas
NDA 018985	ORTHO-NOVUM 7/7/7	Ethinyl Estradiol; Norethindrone	0.035 mg; 0.5 mg, 0.035 mg; 0.75 mg, 0.035 mg; 1 mg	Tablet; Oral	Janssen Pharms.
NDA 019297	NOVANTRONE	Mitoxantrone Hydrochloride	EQ 20 mg Base/ 10 mL, EQ 2 mg Base/mL	Injectable; Injection	EMD Serono Inc.
NDA 019927	NIZORAL	Ketoconazole	2%	Shampoo; Topical	Janssen Pharms.
NDA 020207	ALKERAN	Melphalan Hydrochloride	EQ 50 mg Base/Vial	Injectable; Injection	Apotex Inc.
NDA 020262	TAXOL	Paclitaxel	6 mg/mL	Injectable; Injection	HQ Specialty Pharma
NDA 020281	ULTRAM	Tramadol Hydrochloride	100 mg	Tablet; Oral	Janssen Pharms.
NDA 021692	ULTRAM ER	Tramadol Hydrochloride	100 mg, 200 mg, 300 mg	Tablet, Extended Release; Oral	Valeant Pharms.
NDA 021844	DESONATE	Desonide	0.05%	Gel; Topical	Leo Pharma
NDA 022008	REQUIP XL	Ropinirole Hydrochloride	EQ 2 mg Base, EQ 4 mg Base, EQ 6 mg Base, EQ 8 mg Base, EQ 12 mg Base	Tablet, Extended Release; Oral	GlaxoSmithKline LLC

NDA 050639	CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER	Clindamycin Phosphate	EQ 6 mg Base/mL, EQ 12 mg Base/mL, EQ 18 mg Base/mL	Injectable; Injection	Pfizer
NDA 050684	ZOSYN	Piperacillin Sodium; Tazobactam Sodium	EQ 2 g Base/Vial; EQ 250 mg Base/Vial, EQ 3 g Base/Vial; EQ 375 mg Base/Vial, EQ 4 g Base/Vial; EQ 500 mg Base/Vial, EQ 36 g Base/Vial; EQ 4.5 g Base/Vial	Injectable; Injection	Wyeth Ayerst Pharms.
ANDA 062336	MUTAMYCIN	Mitomycin	40 mg/Vial	Injectable; Injection	Bristol-Myers Squibb

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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